

In the claims

We claim:

1. A method of formulating a solid dosage of thyroid hormone, while avoiding
5 instability caused by interaction of the active ingredient with excipients,
comprising depositing the active ingredient, as a dry powder substantially free of
excipients, onto a pharmaceutically acceptable polymer substrate.
2. The method of claim 1, wherein the depositing is performed electrostatically.
3. The method of claim 1, wherein the thyroid hormone is levothyroxine sodium or
10 triiodothyronine.
4. The method of claim 1, wherein the polymer has received regulatory approval and
15 is of GRAS status.
5. The method of claim 4, wherein the polymer is selected from the group consisting
of polyvinyl alcohol, polyvinyl pyrrolidinone, polysaccharide polymers, acrylate
polymers, methacrylate polymers, phthalate polymers, polyvinyl acetate, methyl
20 cellulose, carboxymethylcellulose, hydroxyethylcellulose,
hydroxypropylcellulose, hydroxypropylmethylcellulose, ethyl cellulose,
Eudragits, starch-based polymers, gelatin, and combinations thereof.

6. The method of claim 4, wherein the polymer is substantially unreactive with an amino group or iodo group in the thyroid hormone molecule.
- 5 7. The method of claim 6, wherein the polymer is selected from the group consisting of hydroxypropylcellulose, hydroxypropylmethylcellulose, ethyl cellulose and combinations thereof.
8. An improved solid pharmaceutical dosage formulation, comprising a therapeutic
10 amount of thyroid hormone, electrostatically deposited on a pharmaceutically acceptable polymer substrate as a dry powder substantially free of excipients, wherein the average powder particle size is less than about 15 μ .
9. The formulation of claim 8, wherein the thyroid hormone is levothyroxine sodium
15 or triiodothyronine.
10. The formulation of claim 8, wherein the average powder particle size is less than about 10 μ .
- 20 11. The formulation of claim 8, wherein the average powder particle size is less than about 5 μ .

12. The formulation of claim 8, wherein the polymer is substantially unreactive with an amino group or iodo group in the thyroid hormone molecule.

13. The method of claim 2, further comprising:

- 5 (a) applying a cover film to encapsulate the electrostatically deposited active ingredient, so as to form a stable core; and
- (b) further processing the stable core into a dosage form resembling a tablet, capsule, caplet, wafer or stamp-like presentation.

109020-4600660